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10/816,252	04/02/2004	David Walter Wright	115624	8511
25944 7590 01/05/2011 OLIFF & BERRIDGE, PLC P.O. BOX 320850 ALEXANDRIA, VA 22320-4850				
EXAMINER				
BOWERS, NATHAN ANDREW				
ART UNIT		PAPER NUMBER		
1775				
NOTIFICATION DATE		DELIVERY MODE		
01/05/2011		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

OfficeAction25944@oliff.com  
jarnstrong@oliff.com

# Office Action Summary

**Application No.**

10/816,252

**Applicant(s)**

WRIGHT ET AL.

**Examiner**

NATHAN A. BOWERS

**Art Unit**

1775

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 August 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-78 is/are pending in the application.
- 4a) Of the above claim(s) 31-55 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5-9, 20-23, 25-30 and 74-76 is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 10-19, 24, 56-66, 70-73, 77 and 78 is/are rejected.
- 7) ☒ Claim(s) 67-69 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09 August 2010 has been entered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1) Claims 71, 72 and 78 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. More specifically, claim 71 states that liquid is maintained at a "level that is below the second chamber opening and above the third chamber opening when the apparatus is tilted at an angle up to 70° in any direction." However, paragraph [0056] of the specification filed 4/2/04 indicates that the angle of tilt is directly dependent on the amount of liquid and gas located within separation chamber 12. The limitations of claim

71 are very broad as they are not contingent on a specified liquid/gas volume, and this implies that the chamber may be tilted at an angle up to 70° regardless of the liquid and gas distribution within the chamber. This is contrary to the specification which suggests that large (i.e. 70°) tilt angles may only be achieved when the apparatus is used to handle only certain liquid volumes.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- 2) Claim 71 is rejected under 35 U.S.C. 102(b) as being anticipated by Oshiyama (US 4976708).

Oshiyama discloses an apparatus for separating gas from a liquid path comprising a chamber (Figure 1:12) having a top, bottom and side walls. A first opening (Figure 1:15) allows gas and liquid to enter the chamber, a second opening (Figure 1:18) is configured to allow gas to exit the chamber, and a third opening (Figure 1:17) is configured to allow liquid to exit the chamber. This is taught in column 4, line 41 to column 6, line 22. Oshiyama discloses a plurality of embodiments (see Figure 1 and 3, for example) in which the second chamber opening is positioned varying locations along the top portion. The apparatus of Oshiyama is fully capable of maintaining a liquid level below the second chamber opening and above the third chamber opening when the

apparatus is tilted at an angle up to 70° in any direction when the chamber is filled with a specified amount of fluid.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

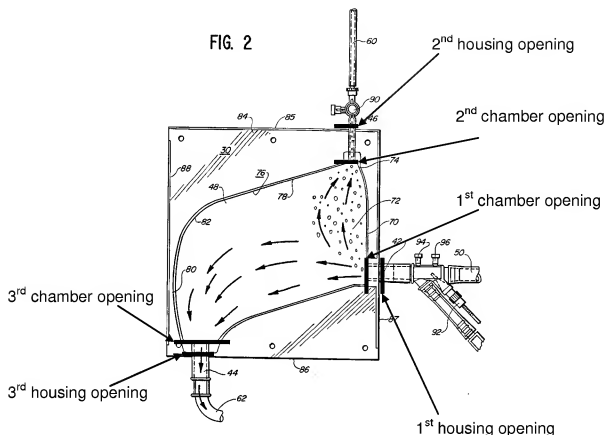
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3) Claims 1, 3, 4, 10-12, 18, 19, 24, 65 and 70-72 are rejected under 35

U.S.C. 103(a) as being unpatentable over Viitala (US 4643713) in view of Oshiyama (US 4976708).

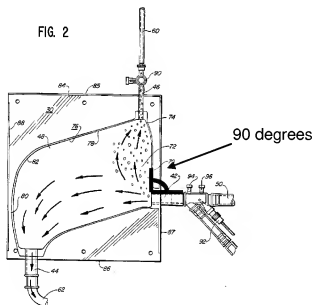
With respect to claims 1, 3, 71 and 72, Viitala discloses an apparatus for separating gas from a liquid path comprising a chamber housing formed by sealing together two plastic sheets (Figure 2:84). A chamber (Figure 2:48) is formed between the sheets and within the chamber housing. This is disclosed in column 3, line 57 to column 4, line 2. The chamber has a top wall (Figure 2:76), sidewalls (Figure 2:70, 80) and a bottom wall. A first chamber opening and a first housing opening serve to allow a liquid and gas to enter the chamber. A second chamber opening and a second housing opening are configured to remove a gas from the chamber, and a third chamber opening and a third housing opening are configured to remove a fluid from the chamber. Column 2, line 58 to column 3, line 15 states that blood moves into the chamber through the first openings, and that air is exhausted from the second openings while air-free blood is removed through the third openings.



A plurality of channels are formed within the housing (between the sealed plastic sheets 84) so that each channel is in fluid communication with a respective chamber opening. Each channel serves to connect a respective housing opening with a corresponding chamber opening. Viitala teaches that no additional structures are positioned within the chamber, and accordingly discloses uninhibited fluid communication between the first, second and third chamber openings.

Although Figure 2 suggests that the second chamber opening is located at the top portion of the chamber, it is not entirely clear whether the second chamber opening is located in the *middle* of the top portion. From Figure 2, it appears that the second

chamber opening is located at one side of the top portion. However, it would have been obvious to ensure that the second chamber opening of Viitala is located in a middle-portion of a top portion. This would represent a mere rearrangement of parts that would not affect the functionality of the device, and instead would only represent a cosmetic design choice. Viitala does not disclose any teachings that require the second chamber opening to be positioned at one side of the top portion. Viitala only states in column 3, lines 22-25 that the sidewall (Figure 2:70) leading to the second chamber opening must be at a sharp right angle with the first chamber opening, but says nothing about the placement of the second chamber opening.

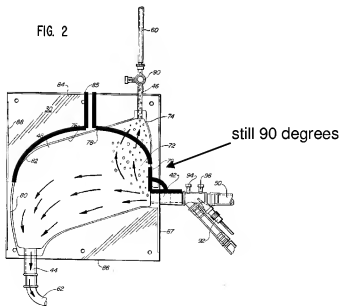


Therefore, one of ordinary skill would have found it obvious to position the second chamber opening anywhere along the top portion of the chamber. This is especially true in light of Oshiyama.



Oshiyama discloses an apparatus for separating gas from a liquid path comprising a chamber (Figure 1:12) having a top, bottom and side walls. A first opening (Figure 1:15) allows gas and liquid to enter the chamber, a second opening (Figure 1:18) is configured to allow gas to exit the chamber, and a third opening (Figure 1:17) is configured to allow liquid to exit the chamber. This is taught in column 4, line 41 to column 6, line 22. Oshiyama discloses a plurality of embodiments (see Figure 1 and 3, for example) in which the second chamber opening is positioned varying locations along the top portion.

Accordingly, one of ordinary skill would have recognized that the Viitala reference could be modified to provide a second chamber opening in a middle portion of the top portion while still maintaining the sidewall (Figure 2:70) leading to the second chamber opening at a sharp right angle with the first chamber opening.



Viitala additionally teaches that third chamber opening is at a bottom portion of the chamber. Viitala, however, does not expressly teach that the third chamber opening is at a *middle* portion of the bottom.

Oshiyama discloses an apparatus for separating gas from a liquid path comprising a chamber (Figure 1:12) having a top, bottom and side walls. A first opening (Figure 1:15) allows gas and liquid to enter the chamber, a second opening (Figure 1:18) is configured to allow gas to exit the chamber, and a third opening (Figure 1:17) is configured to allow liquid to exit the chamber. This is taught in column 4, line 41 to column 6, line 22. Column 5, lines 45-62 state that the third opening is located in a middle portion of the chamber bottom when  $L2/L = 0.5$  (see Figure 1).

Viitala and Oshiyama are analogous art because they are from the same field of endeavor regarding debubbling apparatuses for blood.

At the time of the invention, it would have been obvious to provide the third chamber opening of Viitala at a middle portion of bottom of the chamber rather than to one side. Oshiyama teaches a similar debubbler bag configuration that successfully removes air from a blood stream, wherein the third chamber opening for removing air-free blood is at a middle portion of the chamber bottom. Accordingly, one of ordinary skill would have recognized that a successful gas separating procedure could likewise be completed in the Viitala apparatus if the Viitala third chamber opening was located at the middle of the chamber bottom.

With respect to claims 4, 19 and 24, Viitala and Oshiyama disclose the apparatus in claim 1. As previously set forth above, Viitala indicates that the chamber is located within a housing, and that each housing opening is in fluid communication with the chamber through respective channels. Each channel has a first end at a housing opening and a second end at a chamber opening. See Figure 2. The channel associated with the first opening operates as an entrance for blood, and the channels associated with the second and third openings operate as exits for air and air-free blood, respectively.

With respect to claims 10 and 70, Viitala and Oshiyama disclose the apparatus in claim 1. The debubbler of Viitala further comprises a plurality of connection devices (Figure 2:94, 96) is capable of connecting to either a tube frame, an organ or tissue transporter, a perfusion device, or a diagnostic device. The debubbler is also capable of interacting directly with a blood tube (Figure 2:50) that could in turn be in communication with essentially any organ or tissue device. The debubbler may additionally be operated with liquid in the chamber at a level lower than the second opening when the chamber is on a level support.

With respect to claim 11, Viitala and Oshiyama disclose the apparatus in claim 1. Viitala and Oshiyama each teach that the device is constructed from plastic. Transparent plastic materials are considered to be well known in the art.

With respect to claims 12 and 18, Viitala and Oshiyama disclose the apparatus in claim 3. Viitala further teaches that tubing (Figure 2:60, 50, 64) is connectable to each of the plurality of openings.

With respect to claim 65, Viitala and Oshiyama disclose the apparatus in claim 1. Oshiyama further states in column 5, lines 45-62 that the first chamber opening is located at or near the bottom portion of the chamber when H1/H is approximately 0.

At the time of the invention, it would have been obvious to provide the first chamber opening of Viitala the bottom of the chamber rather than towards the middle. Oshiyama teaches in column 5, lines 45-62 that this fluid opening configuration allows for the successful removal of air from a blood stream. One of ordinary skill would have recognized that a successful gas separating procedure could likewise be completed in the Viitala apparatus if the Viitala first chamber opening was located at the bottom of the chamber.

4) Claims 13-17, 56-64, 66, 77 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Viitala (US 4643713) in view of Oshiyama (US 4976708) as applied to claims 12, 58 and 72, and further in view of Sadri (US 5494822).

With respect to claims 13-17 and 78, Viitala and Oshiyama disclose the apparatus set forth in claim as set forth in the 35 U.S.C. 103 rejection above, however do not expressly state that a sensor is provided for detecting gas moving through the first and/or third housing openings.

Sadri discloses a device for transporting and maintaining an organ that comprises a chamber (Figure 1:25) for holding the organ, a fluid supply line (Figure 1:13) and an oxygenator (Figure 1:6). This is disclosed in column 10, line 34 to column 11, line 6. Column 6, lines 11-20 further state that a bubble trap is provided between the oxygenator and the perfused organ. Sensors (Figure 1:14) monitor gas levels of fluid moving from the bubble trap to the organ chamber. Column 11, lines 50-58 state that the flow rate of perfusate flowing into the organ is altered in response to gas level characteristics measured in the fluid. Column 7, lines 40-60 indicate that the operation of the pumping mechanisms and valves regulating the fluid system are controlled in response to measurements made by the gas sensors. Although Sadri does not specifically disclose the use of an ultrasonic gas sensor, ultrasonic gas sensors are considered to be well known in the art. It would have been obvious to use any known sensor in the apparatus of Sadri.

Viitala and Sadri are analogous art because they are from the same field of endeavor regarding culture means.

At the time of the invention, it would have been obvious to equip the apparatus of Viitala with a gas monitoring probe capable of interacting with a control system designed to regulate fluid flow to and from the debubbler in response to detected gas levels. Since the intent of the Viitala device is to remove gas from a blood stream, one of ordinary skill in the art would have found it obvious to include sensing means capable of determining the efficacy of the system and the extent of gas removal.

With respect to claims 56-64, 66 and 77, Viitala and Oshiyama disclose the apparatus set forth in claim as set forth in the 35 U.S.C. 103 rejection above, however do not expressly state that the debubbler is used in combination with an organ located in an organ transporter.

Sadri discloses the apparatus as previously described above. Sadri teaches the use of a perfused organ (Figure 1:15) positioned within an organ transporter (Figure 1:25). Sadri further teaches in column 6, lines 11-20 that a bubble trap is often required to treat fluid moving through the organ.

At the time of the invention, it would have been obvious to utilize the combination of Viitala and Oshiyama to treat blood moving through an organ located in an organ transporter. Sadri teaches in column 6, lines 11-20 that debubblers are especially applicable to organ perfusion systems because they remove bubbles that could embolize in the organ causing infarction.

***Allowable Subject Matter***

Claims 5-9, 20-23, 25-30 and 74-76 are allowed.

With respect to independent claims 5, 20, 25 and 35, the prior art does not disclose, in the claimed environment, an apparatus for separating gas and liquid comprising housing openings all located on a common housing side wall. The Viitala reference discloses substantially straight inlet and exit channels situated between respective first, second and third chamber openings and housing openings. Viitala, however, does not disclose that the first and third housing openings are located on the

same housing side wall. Viitala does not teach that channels may be rearranged to produce channels of varying shapes and configurations (i.e. providing a horizontal component to the exit channel leading from the third chamber opening, or providing a vertical component to the inlet channel leading to the first chamber opening).

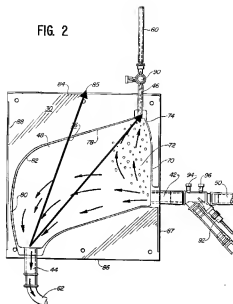
Claims 67-69 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art does not disclose, in the claimed environment, a gas and liquid separation chamber in communication with channels provided according to the configuration set forth in claims 67-69.

### ***Response to Arguments***

Applicant's arguments filed 09 August 2010 with respect to the 35 U.S.C. 103 rejections involving Viitala and Oshiyama have been fully considered but they are not persuasive.

The majority of Applicant's arguments have been fully addressed in previous Office Actions. It is additionally noted that one of ordinary skill in the art would have been able to modify the Viitala apparatus in the manner proposed in the rejections above while still allowing "the outlet 44 [to be] diagonally spaced as far as possible from vent 46" simply by moving vent 46 closer to the top of the housing.



Outlet vent 46 could easily be moved to the center of the chamber while still maintaining approximately the same diagonal distance between outlet vent 44 and outlet vent 46.

Alternatively, it is also noted that Oshiyama's expressed indifference to the location of each vent port (as asserted by Applicant), if found to be an accurate interpretation of Oshiyama, is actually considered to be even more evidence that the relative placement of Viitala's vents may be adjusted. Oshiyama's broad and general approval of a wide range of permissible vent positions would have encouraged those of ordinary skill to experiment with various vent placements within the debubbler of Viitala.

### ***Conclusion***

This is a non-final rejection.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN A. BOWERS whose telephone number is (571)272-8613. The examiner can normally be reached on Monday-Friday 7 AM to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on (571) 272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nathan A Bowers/  
Primary Examiner, Art Unit 1775